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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,476	12/07/2001	Norbert O. Reich	G&C 30794.30-US-D1	8266

7590 02/23/2004

Attn: Karen S. Canady
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Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, CA 90045

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,476

Applicant(s)

REICH ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed November 26, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 22 and 32 have been amended.

Claim 31 has been canceled.

Remarks drawn to rejections of Office Action mailed August 26, 2003 include:

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

103(a) rejection: which has been overcome by applicant's amendments and arguments and has been withdrawn.

An action on the merits of claims 21-27 and 32-35 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21, 24 and 33-35 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Sufrin et al. (US Patent 5,652,105).

Claim 21 is drawn to a method of inhibiting the methylation of DNA comprising contacting a DCMTase with a synthetic inhibitor molecule in the presence of DNA wherein the inhibitor molecule comprises a C-5 methylcytosine molecule which binds to an allosteric site on the DCMTase, which inhibits the methyltransferase activity. Claim 24 provides that the inhibitor is an oligonucleotide comprising the C-5 methylcytosine molecule. Claim 33 provides that the subject is human, claim 34 provides the subject is an animal, and claim 35 provides the animal is porcine, piscine, avian, feline, equine, bovine, ovine, caprine, or canine.

Sufrin et al. disclose an oligomeric DNA analog which comprises at least one 5-methylcytosine residue which specifically interacts with mammalian DCMTase (abstract). Moreover, Sufrin et al. disclose that their analogs are useful to inhibit DNA methyltransferase activity in tumor cells (column 3, lines 28-33). Sufrin et al. additionally disclose that their analogs appear to interact with both an activation and a catalytic site on the enzyme (column 7, lines 29-31). Moreover, Sufrin et al. disclose that their analogs were artificially constructed (column 4, lines 54-58). Sufrin et al. disclose that their analogs are effective in inhibiting DCMTase activity in humans (column 1, lines 42-53) as well as mice (column 2, lines 52-61).

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The disclosure of Sufrin's 5-methylcytosine containing oligomeric DNA and their use of the same to inhibit mammalian DCMTase activity is seen to anticipate claims 21, 24, and 33-35 of the instant application.

Claims 22-23, 25-27, and 32 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Sufrin et al. (US Patent 5,652,105).

Claim 22 is drawn to a method of inhibiting the proliferation of cancer cells comprising administering a synthetic inhibitor molecule that comprises a C-5 methylcytosine molecule which binds to an allosteric site on the DCMTase, which inhibits the methyltransferase activity. Claim 23 provides that the cancer is from lung, breast, prostate, pancreas, or colon. Claim 25 provides that the subject is human, claim 26 provides the subject is an animal, and claim 27 provides the animal is porcine, piscine, avian, feline, equine, bovine, ovine, caprine, or canine. Claim 32 provides that the inhibitor is an oligonucleotide comprising the C-5 methylcytosine molecule.

Sufrin et al. disclose an oligomeric DNA analog which comprises at least one 5-methylcytosine residue which specifically interacts with mammalian DCMTase (abstract). Moreover, Sufrin et al. disclose that their analogs are useful to inhibit DNA methyltransferase activity in tumor cells (column 3, lines 28-33). Sufrin et al. additionally disclose that their analogs appear to interact with both an activation and a catalytic site on the enzyme (column 7, lines 29-31). Moreover, Sufrin et al. disclose that their analogs were artificially constructed (column 4, lines 54-58). Sufrin et al. disclose that their analogs are effective in inhibiting DCMTase activity in humans (column 1, lines 42-53) as well as mice (column 2, lines 52-61).

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Moreover, Sufrin disclose that lowering the level and activity of DCMTase also lowers the incidence of colon cancer (column 2, lines 52-61).

The disclosure of Sufrin's 5-methylcytosine containing oligomeric DNA and their use of the same to inhibit mammalian DCMTase activity and the disclosure of inhibiting DCMTase activity in decreasing methylation which lowers incidence of cancer is seen to anticipate claims 22-23, 25-27, and 32 of the instant application.

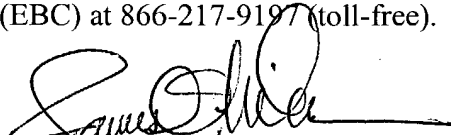
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657.

The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh III
February 19, 2004